



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DEC 22 1993

Gerald D. Rosebery, Ph.D.
International Regulatory Consulting
118 Fourth Street, S.E.
Washington, DC 20003

SUBJECT: Case 4026, AI 024002, ~~Copper~~ 8-Quinolinolate
Review of GDLNs 81-1, 81-2, 81-5 and 81-6

Dear Dr. Rosebery:

This letter addresses the review of MRIDs 42921501 - Determination of the Acute Oral Toxicity in the Rat; 42921502 - Determination of the Acute Dermal Toxicity in the Rat; 42921503 - Primary Skin Irritation Study in Rabbits; and 42921504 - Contact Hypersensitivity in Albino Guinea Pigs. These studies were submitted to fulfill GDLN requirements for 81-1, 81-2, 81-5 and 81-6, respectively, for AI 024002, copper 8-quinolinolate.

Guideline 81-1 - Acute Oral Toxicity

MRID 42921501, Determination of Acute Oral Toxicity of Ro 17-0099/000 (copper 8-quinolinolate) in the Rat, is acceptable and fulfills the requirements for an acute oral toxicity study. The LD₅₀ in both sexes of Sprague-Dawley rats is greater than 5000 mg/kg. Copper 8-quinolinolate meets the criteria for oral toxicity category IV. GDLN 81-1 is satisfied. No further data are required.

Guideline 81-2 - Acute Dermal Toxicity

MRID 42921502, Determination of Acute Dermal Toxicity of Ro 17-0099/000 (copper 8-quinolinolate) in the Rat, is acceptable and fulfills the requirements for an acute dermal toxicity study. The LD₅₀ in both sexes of Fullinsdorf albino rats is greater than 2000 mg/kg. Copper 8-quinolinolate meets the criteria for dermal toxicity category III. GDLN 81-2 is satisfied. No further data are required.

Guideline 81-5 Primary Dermal Irritation

MRID 42921503, Primary Skin Irritation Study with Ro 17-0099/000 (copper 8-quinolinolate) in Rabbits (4-Hour Semi-Occlusive Application on Intact and Abraded Skin), is acceptable and fulfills the requirements for a dermal irritation study. Copper 8-quinolinolate does not appear to cause primary dermal irritation in New Zealand white rabbits of both sexes and meets the criteria for dermal toxicity category IV. GDLN 81-5 is satisfied. No further data are required.

Guideline 81-6 Dermal Sensitization

MRID 42921504 , Contact Hypersensitivity in Albino Guinea Pigs with Ro 27-0099/000 (copper 8-quinolinolate) - Maximization Test, is acceptable and fulfills the requirements for a dermal sensitization study. The copper 8-quinolinolate does not appear to be a dermal sensitizer in albino guinea pigs under the study conditions utilized. GDLN 81-6 is satisfied. No further data are required.

Copies of the four DERs are enclosed for your records. If you have any questions, please contact Kathleen Depukat of the Accelerated Reregistration Branch at 703-308-8587.

Sincerely yours,

Kathy Davis

Kathy Davis, Section Chief
Reregistration Section 2
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Enclosures

cc: Sheryl K. Reilly, HED
Cynthia Giles-Parker, RD ✓

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